In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0344V

JESSICA RAMIREZ, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: August 16, 2024

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Parisa Tabassian, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE[1]

On January 8, 2021, Jessica Ramirez filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] (the "Vaccine Program"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") following her receipt of an influenza ("flu") vaccine which she received on September 1, 2020. Petition (ECF No. 1); *see also* Amended Petition filed July 18, 2022 (ECF No. 20). Respondent argues that the claim cannot meet the Vaccine Act's "severity requirement," *see* Section 11(c)(1)(D)(i). For the reasons stated below, I deem the claim appropriately dismissed on that basis.

[1] Because this decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

I. Procedural History

The claim was assigned to the "Special Processing Unit" (OSM's adjudicatory system for expedited resolution) (ECF No. 15). Respondent was opposed to any exploration of settlement, however, and filed his Rule 4(c) Report, disputing satisfaction of the severity requirement and requesting that Petitioner obtain certified and complete records. Rule 4(c) Report filed July 10, 2023 (ECF No. 29). I ordered Petitioner to show cause why the claim should not be dismissed on those bases. Show Cause Order filed Oct. 3, 2023 (ECF No. 30).

Petitioner subsequently filed Exs. 10 – 17 (*see* ECF Nos. 33 – 38), and the parties briefed the disputed issues. Petitioner's Response to Order to Show Cause filed Feb. 5, 2024 (ECF No. 39) (hereinafter "Brief"); Respondent's Response filed Feb. 15, 2024 (ECF No. 40); Petitioner's Reply filed Mar. 18, 2024 (ECF No. 41). The matter is now ripe for adjudication.[3]

II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

[3] It is noted that the Rule 4(c) Report and the parties' briefing contain citations to Exhibits 4, 5, and 8 – which are not certified as accurate and complete. This opinion instead utilizes citations to the *certified* records from those providers, which have been filed as Ex. 12 (replacing Ex. 4) and Ex. 13 (replacing Exs. 5 and 8). *See also* Reply at n. 1.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A potential petitioner must demonstrate that he or she "suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." Section 11(c)(1)(D)(i)[4]; *see also Black v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a *prima facie* case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

[4] Section 11(c)(1)(D) presents two alternative grounds for eligibility to compensation if a petitioner does not meet the six months threshold: (ii) death from the vaccine, and (iii) inpatient hospitalization and surgical intervention. Neither alternative is alleged or implicated in this claim.

Congress has stated that the severity requirement was designed "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied,* 132 S.Ct. 1908 (2012); *Wright v. Sec'y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

III. Evidence

The medical records reflect that Petitioner was born in 1942. In summer 2018, she reported right-sided neck, shoulder, and arm pain. Ex. 3 at 99, 177. A physical therapist documented right shoulder cuff weakness and pain with elevation. *Id.* at 177. The therapist assessed scoliosis, muscle imbalance, and a poor sleeping arrangement, for which further PT was recommended. *Id.* at 177. However, Petitioner did not seek further treatment for, or renew, this complaint. *See generally* Ex. 3. Petitioner also attended regular medical appointments for chronic issues including heart failure, atrial fibrillation (requiring a pacemaker), hypertension, and anemia. *See, e.g.*, Ex. 3 at 121 – 25.[5]

Petitioner received the at-issue flu vaccine intramuscularly in her right deltoid at a Walgreens pharmacy on September 1, 2020. Ex. 1 at 1 – 2.[6] Petitioner was not documented to have complained of right shoulder pain during subsequent primary care encounters focused on other issues on September 2, and September 10, 2020. Ex. 3 at 67 – 74.

Nineteen days (19) days post-vaccination, on September 20, 2020, Petitioner sought urgent care for a chief complaint of "right arm pain from flu shot on Sept 1." Ex. 2 at 42. The pain was exacerbated by activity, movement, and palpation; rated 5/10; "sho[t] down her arm"; and was disrupting her sleep. *Id.* at 43. Tylenol, heat, and rest had not relieved the pain. *Id.* Physical examination of the musculoskeletal system found "normal ROM, normal strength, proximal upper extremity: right shoulder – no tenderness, no

[5] Of note, Ex. 3 at 121 – 25 is one example of a medical encounter with a specialist (here, with a cardiologist) that is embedded within the primary care records, and a medical encounter did not listed in Petitioner's medical history. *See* PAR Questionnaire (ECF No. 13) at 1 (instructing Petitioner to list "*All* medical offices and/or medical facilities where [she] ha[d] been seen during the three (3) years prior to vaccination [and] *All* offices or facilities where [she] received treatment following the vaccination(s), *even if unrelated to the vaccine injury*.") (emphasis added).

[6] Exhibit 1 is not certified as accurate and complete, as noted in Response at n. 1. On March 18, 2024, Petitioner replied that she has submitted another request to Walgreens for the records at issue, which Petitioner promised to file upon receipt. Reply at n. 1. Certified copies of those records have not been received. *But see* Ex. 3 at 120 (Walgreens vaccine administration record, embedded within certified primary care records).

swelling, no erythema." *Id.* at 45. A nurse practitioner proposed that Petitioner "most likely has some nerve pain after vaccination," and prescribed diclofenac topical gel, a Medrol dosepak (oral steroids, to take for six days), and tramadol (12 tabs with no refills, "for severe pain only"). *Id.* The NP also recommended Tylenol, ice, heat, gentle stretching – and provided patient educational materials about musculoskeletal pain. *Id.*

On October 8, 2020, Petitioner's primary care provider ("PCP") recorded her history of right shoulder pain since vaccination, which had been temporarily relieved by the steroids but had subsequently increased in severity. Ex. 3 at 66. Petitioner reported her current pain as 8/10, particularly associated with raising the arm. *Id.* The PCP recorded that on exam, there was "no limited arm but has pain on deltoid when she moves it." *Id.* The PCP assessed a soft tissue injury, for which she prescribed gabapentin. *Id.* at 65.

On December 23, 2020, Petitioner secured orthopedist John Klein, M.D.'s referral for an x-ray of her right shoulder, which found: "[s]ignificant subacromial impingement with external rotation and abduction." Ex. 12 at 5. The next day, Dr. Klein reviewed Petitioner's history of right shoulder pain had persisted since her flu shot in September 2020. Ex. 12 at 3 – 4. Dr. Klein's exam found "diffuse pain [and] positive weakness with resisted external rotation." *Id.* at 3. He did not offer any assessment or treatment plan – waiting to determine Petitioner's "pacemaker profile," which might contraindicate an MRI. *Id.*

At a January 14, 2021 follow-up appointment, Dr. Klein made identical exam findings, and his tentative assessment was a rotator cuff tendon tear. Ex. 12 at 6. Because Petitioner had a pacemaker and could not undergo an MRI, Dr. Klein planned an ultrasound of her shoulder, but it was never obtained. *Id.* 6 – 7. Dr. Klein also recorded that Petitioner "[did] not want another injection." *Id.* at 6. He did not offer any treatment plan. *Id.* There are no further records from Dr. Klein.

Over the following eight months, Petitioner attended numerous, in-person medical encounters focused on chronic issues – primarily relating to her heart. At a January 29, 2021, cardiology appointment, Petitioner reported not exercising as much due to recent chest heaviness, palpitations, and shortness of breath. Ex. 13 at 408. At a February 25, 2021, cardiology follow-up, she reported "more" chest heaviness, plus shortness of breath and headaches. *Id.* She apparently underwent an angiogram on March 16, 2021. *Id.*

At a March 24, 2021, cardiology follow-up, Petitioner "denie[d] any recurrent chest pain but state[d] that she has no energy"; she apparently had made an appointment to

see Peter Ott, M.D.,[7] in mid-April. Ex. 13 at 408. The following day, the PCP saw Petitioner for a visit diagnosis of atrial fibrillation, but the medical record only reflects updates to her medication list, and lab work. Ex. 13 at 385 – 90. There is no recorded history, exam, assessment, or plan – and no information relating to Petitioner's shoulder.

The PCP records also reflect the intramuscular administration of COVID-19 vaccines in Petitioner's right arm (the same arm as the alleged SIRVA) at a Walgreens on May 3, and May 24, 2021. Ex. 13 at 276 – 77.

At a July 30, 2021, cardiology follow-up, Petitioner reported feeling poorly, not sleeping well, and experiencing palpitations and dizziness. Ex. 13 at 408. She "had a monitor placed for a week" and was scheduled to follow up with Dr. Ott in August *Id.* Petitioner also underwent lab work at the primary care office on at least nine dates during this intervening time period. Ex. 13 at 449 – 51 (billing summary); *id.* at 287 – 380 (corresponding medical records).

On September 10, 2021, Petitioner presented to her PCP for to "follow up" on right shoulder pain. Ex. 13 at 271. The PCP recorded Petitioner's history that she had been experiencing ongoing right should pain "due to" her flu vaccine a year ago. *Id.* The PCP's exam found "right shoulder pain on abduction over 90." *Id.* at 272. The assessment was "right shoulder pain unspecified chronicity." *Id.* at 274. A flu vaccine was administered in Petitioner's left arm. *Id.* at 276.

The PCP also ordered a CT scan, which lists a clinical indication of "chronic right shoulder pain for one year." Ex. 9 at 3. The scan revealed mild glenohumeral and acromioclavicular osteoarthritis and moderate sternoclavicular osteoarthritis. *Id.*

At an October 28, 2021, annual exam, the PCP's exam found right shoulder "pain on abduction over 90 degrees," and she offered a referral to an orthopedic surgeon, Joel Thompson, M.D. Ex. 13 at 200, 204. However, Petitioner never presented to Dr. Thompson, *see* Ex. 11, or received any other treatment for her shoulder.

I have also reviewed the submitted affidavits. Petitioner maintains that her right shoulder pain from the flu vaccine continued throughout 2021. Ex. 6 at ¶¶ 5 – 8. She also states that she deferred treatment for this injury for much of 2021 to reduce the risk that she, and her husband (who is approximately twelve years older than her), would contract COVID. Ex. 7 at ¶ 2.

[7] Dr. Ott is identified elsewhere as the physician "managing" Petitioner's pacemaker. Ex. 13 at 411. No records from this provider have been filed.

In December 2023, her three adult children recalled that Petitioner's right shoulder injury had persisted throughout 2021. Her son only recounts telephone calls, particularly relating to the September 2020 onset of her injury – and thus his affidavit is less helpful to resolving severity. *See generally* Ex. 16.

Her daughters recall a specific telephone call with Petitioner about right shoulder pain on March 16, 2021. *See generally* Exs. 14, 17; *see also* Ex. 15 (group text message from that date encouraging prayers for Petitioner, and photos of Petitioner on subsequent dates). The daughters also recall personally witnessing Petitioner with a right shoulder injury while visiting her in late March 2021 and beyond. *See generally* Exs. 14, 17. One daughter also recalls that on March 25, 2021, the PCP "felt [Petitioner] was experiencing a bit of depression due to her inability to do the things she loves because of her arm." Ex. 14 at ¶ 4; *but see* Ex. 13 at 385 – 90 (not corroborating this memory).

IV. Respondent's Rule 4(c) Report and Show Cause Analysis

To meet the statutory severity requirement, Petitioner must preponderantly establish that she suffered a shoulder injury from the September 1, 2020, vaccine for at least six months thereafter – here, until March 1, 2021.

When I issued my Show Cause Order, I stated that the case-specific evidence, particularly the medical records, were highly relevant to judging severity. Show Cause Order at 3. I also tentatively concluded that the evidence reflected a mild injury lasting approximately four and one-half months post-vaccination, followed by an unexplained eight-month treatment gap. Petitioner's assertion that 2021 was "the height of the Pandemic," Ex. 7 at ¶ 2, was not particularly persuasive in explaining this treatment gap – particularly because *Petitioner herself* attended in-person encounters with at least three different providers throughout the gap period, which occurred while the Pandemic was already underway rather than at its start in March 2020. Show Cause Order at 2 – 3.

In addition, the treatment gap pointed towards an injury that was resolving and/or self-manageable via conservative measures. Show Cause Order at 3. Moreover, Petitioner had not yet provided any corroborating fact witness affidavits and/or other non-medical evidence that would help to establish the severity requirement. *Id.* I acknowledged that the subsequent PCP records documented some objective findings of a right shoulder injury, which Petitioner related back to the flu vaccine occurring one year earlier. *Id.* But it was crucial for Petitioner to ensure that the evidence was complete, to allow for a comprehensive analysis. *Id.*

V. Responses and Further Analysis

In arguing that she can establish severity, Petitioner emphasizes the medical records documenting a right shoulder injury in January 2021 and again in September 2021; the lack of evidence affirmatively stating that the earlier injury would self-resolve, or point to an alternative cause; her stated fear of the Pandemic; and her supporting affidavits. *See generally* Brief and Reply.

Respondent, by contrast, maintains his objection on this point – agreeing with my earlier analysis that the treatment gap pointed towards an injury that was resolving and/or self-manageable via conservative measures. Reply at 6. And Respondent notes that the treatment gap "spanned the time when COVID-19 vaccines became generally available for all Americans in spring 2021." *Id.*[8] Witness statements to the contrary should be afforded little to no weight based on their late preparation, and that the contemporaneous photos and text messages are not specific to a shoulder injury. *Id.*

After reviewing both parties' arguments and all evidence submitted, I conclude that Petitioner has not preponderantly established that her post-vaccination right shoulder injury or its residual effects persisted for over six months. The record clearly establishes that Petitioner's injury was relatively mild – as evidenced by her 19-day delay in medical treatment and subsequent conservative course, which involved just four evaluations and imaging over approximately four and one-half months post-vaccination. I recognize the high pain ratings and limited courses of prescription pain medications, but she appears to have relied mostly on Tylenol and other conservative measures. She did not pursue any steroid injections, PT, or surgery. And as Respondent contends (Response at 8), movement of the shoulder was painful, but not objectively limited. It is thus reasonably possible that a mild injury could resolve short of the six-month cut-off.

In addition, the treatment gap in this case, which spans the severity cut-off date, corroborates the conclusion that Petitioner's injury had more likely than not resolved. Petitioner has not adequately addressed the eight-month gap in any documentation or treatment of a right shoulder injury. I have considered Petitioner's contentions that she wished to avoid treatment due to concerns of COVID, but the record shows that she attended at least fifteen (15) in-person encounters for other concerns during this period. Those records are silent on the subject of her right shoulder. This course of conduct reveals a patient willing to seek treatment for actual concerns – and one who easily could

[8] Citing U.S. Dep't of Health & Hum. Servs., *COVID-19 Vaccines*, https://www.hhs.gov/coronavirus/covid-19-vaccines/index.html (last accessed Aug. 15, 2024) (providing a timeline of "COVID-19 Vaccine Milestones").

have also sought treatment for a shoulder issue had she been experiencing symptoms at the time.

Most glaringly, the record reveals that Petitioner in fact received her first two doses of the COVID-19 vaccine[9] intramuscularly *in her at-issue right arm* in May 2021 (approximately eight months after the at-issue flu vaccine). It is difficult to accept that Petitioner would have accepted these additional vaccines if she was suffering from ongoing right shoulder pain. And they represent a potential alternative cause for any subsequent shoulder injury. Those vaccines are not addressed in the subsequent medical records or the affidavits – which are not sufficiently persuasive to surmount the concerns discussed herein.[10] Overall, I cannot find preponderant evidence that Petitioner suffered a right shoulder injury or its residual effects from the September 1, 2020, vaccine for over six months.

Conclusion

Petitioner has not established the statutory severity requirement. Therefore, she is ineligible to pursue compensation under the Program. In the absence of a timely-filed motion for either reconsideration or review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this Decision.[11]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[9] COVID-19 vaccines are not currently covered under the Vaccine Program.

[10] *See also Leming v. Sec'y of Health & Hum. Servs.*, 161 Fed. Cl. 744, 760 (2022) (declining to impute any "lack of sincerity or bad faith" to a witness's later recollections of what a medical provider had advised, when that advice was not recorded in the contemporaneous medical records), *not disturbed on appeal*, 98 F.4th 1107 (Fed. Cir. 2024).

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.